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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,890	11/20/2003	W. Henry Wall	12310-1140	9411

24504 7590 04/19/2005

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EXAMINER	
MITCHELL, TEENA KAY	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,890	WALL, W. HENRY	
	Examiner	Art Unit	
	Teena Mitchell	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

While applicant in the first paragraph of the specification has noted that the instant application is a continuation-in-part of US application 10/046,767 applicant is required to list the current status of the 10/046,767 application. Correction is required.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: dashed line 50. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Paragraph [00024] open end 28, then in paragraph [00025] air passages 28, then in paragraph [00035] air passages or channels 28 applicant should label reference numeral 28 consistently throughout the disclosure. In paragraph [00024] side ports 30 then in

paragraph [00026] radial protrusions 30 applicant should label reference numeral 30 consistently throughout the disclosure. Correction is required.

Claim Objections

Claims 1-6 and 13 are objected to because of the following informalities: The claimed method steps in claims 1-5 and 13 are not in the specification but only in the claims. With respect to claim 6, line 19, "...said conduit..." lacks antecedent basis. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. **Determining the scope and contents of the prior art.**
2. **Ascertaining the differences between the prior art and the claims at issue.**
3. **Resolving the level of ordinary skill in the pertinent art.**
4. **Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Claims 1-7 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall (CA 1,161,720) in view of Schaller (5,555,890).

Wall in an oro-pharyngeal airway device discloses an airway (10) having a conduit (18) extending there through and extending from the mouth of the patient to the larynx of the patient (Figs. 1, 4, 5), a first nipple (at 22) and a second nipple (at 28). Walls does not disclose a carbon dioxide monitor.

Schaller in an airway device teaches a carbon dioxide monitor (32) in line with a suction means (26) providing a means for measuring end-tidal CO2 in a patient (Col. 1, lines 54-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the oro-pharyngeal airway device of Wall to employ any well known carbon dioxide monitor at the second nipple of Wall doing so would have provided a means to measure end-tidal CO2 including the carbon dioxide monitor taught by Schaller because the CO2 monitor of Schaller is in line with a suction means as is the second nipple of Walls. The claimed method steps would have been obvious because they would have resulted from the use of the device of Walls/Schaller.

With respect to claim 2, the method steps would have been obvious because they would have resulted from the use of the device of Walls/Schaller the steps of intermittently withdrawing and injecting gas to a patient would have been obvious because one of ordinary skill in the art would know that an intermittent withdrawing of a breath would ensure that the patient is also receiving appropriate gas to breath, therefore it would have been obvious to alternate withdrawing gas and then injection gas so the patient is properly oxygenated during the procedure of monitoring the carbon dioxide.

With respect to claim 3, Wall discloses a first nipple (at 22) and a second nipple (at 28), which intersects the air conduit (Fig. 1). The method steps would have been obvious because they would have resulted from the use of the device of Walls/Schaller.

With respect to claim 4, Walls discloses one end of a flexible open ended tube (at 22) to the airway in communication with the air conduit (18) Schaller teaches a carbon dioxide monitor (32) in line with a suction means therefore it would have been obvious to one of ordinary skill in the art to have the other open ended tube (at 28) to a carbon dioxide monitor.

With respect to claim 5, the claimed method steps would have been obvious because they would have resulted from the use of the device of Walls/Schaller.

With respect to claim 6, Walls discloses an oro-pharyngeal airway (10) for insertion into a person's throat comprising: an elongate body (11) having a proximal end and a distal end, said proximal end of said body sized and shaped for engagement by a person' mouth and having a radially extending member (23, 24) configured to block the movement of said proximal end into the patient's mouth, said body being of a predetermined length so that when said proximal end is at the patient's mouth said distal end is positioned at the person's larynx (Fig. 4), said elongate body defining an open ended passage extending through the length of said body and being open at the proximal and distal ends of said body (Figs. 1, 4, 5), a nipple (at 22) extending beyond said radially extending flange , said nipple having an opening that is co-extensive with said open ended passage, a radially extending conduit (at 28) having a passage there through in communication with said open ended passage of said elongate body and

said opening of said nipple (at 22), for the passage there through of breath exhaled from the area of the patient's larynx, protrusions (19, 20, 130, 132, 154, 155) extending from the elongated body shaped to engage the facing surfaces of the throat of the patient and form a breathing passageway along and externally of said conduit means, Schaller teaches a carbon dioxide monitor for detecting the carbon dioxide receive through the conduit of said body from the distal end of the body at the larynx of the patient. With respect to the process of making the suction airway, the limitations of the claim are directed to a process of how the suction airway is formed/molded and therefore, patentable weight is only given to the product by process and not the process itself. In the instant case the product being the suction airway device. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Applicant on page 8 also, states that the gas assisted injection method is any conventionally known method.

With respect to claim 12, Walls discloses an oro-pharyngeal airway (10) for insertion in the throat of a patient, said airway having a proximal end for placement a the patient's mouth and a distal end for placement through the patient's throat adjacent the larynx of the patient (Figs. 1, 4, 5), said airway defining an open ended, approximately cylindrical passage there through (Figs. 1, 4, 5), ribs (19, 20, 130, 132,

154, 155) extending externally along the length of the airway for engagement with the facing surface of the throat of the patient for forming an external passage about the airway so that the patient can breath about the airway, a nipple (at 22) at said proximal end of said airway extending co-extensively from said passage for connection with a suction device or an insufflation device, a protrusion (23, 24) at said proximal end of said conduit between said nipple (at 22) and said conduit fro engagement by the lips of the patient to prevent the proximal of the airway from entering the mouth of the patient, a T-connection (Fig. 1) formed between said protrusion and said nipple and an orifice (at 28) extending through said T-connection to said passage of said airway for controlling the movement of breath exhaled from the patient through said passage, and Schaller teaches a carbon dioxide monitor in communication with said T-connection for detecting the carbon dioxide in the patient's breath received from about the larynx without having passed through the mouth of the patient.

With respect to claim 13, With respect to the process of making the suction airway, the limitations of the claim are directed to a process of how the suction airway is formed/molded and therefore, patentable weight is only given to the product by process and not the process itself. In the instant case the product being the suction airway device. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to claim 14, Wall discloses wherein said T-connection is of grater cross sectional area than said central passage of said oral airway and forms a plenum for accumulating the exhaled breath of the patient (Fig. 1).

With respect to claim 15, Wall does not disclose the plenum at least twice the breadth as the central passage. Applicant has not disclosed that having the plenum at least twice the breadth as the central passage solves any stated problem. Moreover, it appears that the airway device would perform equally well with plenum any size. Accordingly, the use of the plenum twice the breadth as the central passage is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Wall.

With respect to claim 16, Walls discloses an oro-pharyngeal airway device (10) for insertion in the throat of a patient, said airway having an elongated body (11) with a proximal end for placement at the patient's mouth and a distal end for placement through the patient's throat adjacent the larynx of the patient (Fig. 4), said elongated body of said airway defining an open ended passage there through (Figs. 1, 4, 5), ribs (19, 20, 130, 132, 154, 155) extending externally along the length of said elongated body of the airway for engagement with the facing surface of the throat of the patient for forming an external passage about the airway so that the patient can breath about the airway, a nipple (at 22) at said proximal end of said elongated body of said airway and defining a passage extending co-extensively from said open ended passage of said

elongated body, a T-connection (Fig. 1) formed at said nipple with a passage of the T-connection intersecting the passage of said nipple (at 22) and the open ended passage of said elongated body, Schaller teaches a breath monitor detecting the content of the patient's breath received from about the larynx without having the breath passed in contact with the mouth of the patient. With respect to the limitation of said T-connection forming a plenum of a breadth greater than the breadth of said airway for receiving the exhaled breath of the patient see rejection of claim 15 above.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wall/Schaller as applied to claim 1 above, and further in view of Linden (4,882,867).

The difference between Wall and claim 8 is a color applied to said airway that is in contrasting color with respect to said body to denote a pre-selected identifying external size of said body.

Linden in a dental instrument teaches a colored ring (4, 5, 7) providing a means to quickly identify different instruments differing in respect of size, shape, etc. and able to withstand autoclaving process the ring in contrasting color with the instrument (Col. 1, lines 15-59).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the airway device of Wall to employ any well known colored ring doing so would have provided a means to quickly identify different instruments differing in size, and able to withstand autoclaving process including the color ring taught by Linden.

With respect to claim 9, Linden teaches the color differing in respect to size and shape (Col. 1, lines 15-59).

With respect to claim 10, note rejection of claim 15 above.

With respect to claim 11, Wall discloses wherein said plenum is positioned at said radially extending conduit for placement outside the patient's mouth (Figs. 1, 4, 5).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell
Examiner
Art Unit 3743
April 15, 2005